REMARKS

Claims 21-28, 32-34, and 63-65 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai et al. (US 4,659,696).

The Applicant respectfully traverses the rejection.

A rejection for anticipation under Section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

Hirai et al. teaches a pharmaceutical composition for oral or vaginal administration. More particularly, Hirai relates to pharmaceutical compositions for non-oral and non-injection administration, affording a high level of bioavailability.

The compositions disclosed by Hirai et al. contain:

(1) a hydrophilic drug that is poorly absorbable through the gastrointestinal tract; and

(2) a cyclodextrin.

The hydrophilic drug is, for example, a polypeptide such as LH-RH or an analogue thereof having the formula:

$$(Pyr)Glu\text{-}R^1\text{-}Trp\text{-}Ser\text{-}R_2\text{-}R_3\text{-}R_4\text{-}Arg\text{-}Pro\text{-}R_5 \quad (II),$$

in which

R^1 is His, Trp, Tyr, or p-NH_2Phe;

R_2 is Tyr or Phe;

R_3 is Gly or a D-amino acid;

R_4 is Leu, Ile, Nle; and

R_5 is $GlyNHR_6$ or $-NHR_6$ in which R_6 is hydrogen or a lower alkyl optionally substituted by a hydroxyl.

An example of an LH-RH analogue disclosed by Hirai et al. is leuproreline, which has the above formula (II) in which R^1 is His, R_2 is Tyr, R_3 is D-Leu, R_4 is Leu, and R_5 is Net, referred to as TAP-144. Examples 3, 4, and 9 of Hirai et al. describe a nasal composition containing TAP-144 and α-cyclodextrin, and Example 5 discloses a nasal composition containing LH-RH and α-cyclodextrin.

Significantly, the Hirai et al. reference does not disclose the pharmaceutical compositions of the present invention which are appropriate for oral administration and which are suitable for the gastrointestinal delivery of an LH-RH peptide analogue, wherein the α-cyclodextrin enhances the biological activity of the LH-RH peptide analogue when orally administered.

While the preamble of a claim does not usually limit the scope of the claim when it merely states a purpose or intended use of the invention, terms appearing in a preamble may be deemed limitations of a claim when they "give meaning to the claim and properly define the invention", *In re Paulsen*, 30 F.3d 1475, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994).

Furthermore, a recitation in the preamble of a functional property of a chemical compound has been deemed a limitation of the claim, rather than merely an intended use. *Ex parte Schundehutte and Trautner*, 184 USPQ 697, 698 (BPAI held to

The preamble of the composition claim in the present application recites that the pharmaceutical composition is for the gastrointestinal delivery by oral administration of an LH-RH peptide analogue which comprises a therapeutically effective amount of a peptide analogue in combination with α-cyclodextrin and excipients suitable for the gastrointestinal delivery of the peptide analogue, wherein the α-cyclodextrin enhances the biological activity of the LH-RH peptide analogue when orally administered, said LH-RH peptide analogue having the formula (SEQ ID N°: 1).

It is clear that the characterization of the claimed composition as a pharmaceutical composition for the gastrointestinal delivery by oral administration of an LH-RH peptide analogue in combination with α-cyclodextrin, wherein the α-cyclodextrin enhances the biological activity of the LH-RH peptide analogue when orally administered, "breathes life and meaning into the claims", *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 866, 228 USPQ 90, 92 (Fed. Cir. 1984), and therefore distinguishes the claims over the composition of Hirai et al.

Accordingly, the rejection under 35 USC 102(b) should be withdrawn.

Claims 21-28, 32-41, 45-52, 58-65, and 66-78 stand rejected under 35 USC 103(a) as being unpatentable over Hirai et al. in view of Mehlem (US 2003/0162721).

For the reasons expounded above, the Hirai et al. reference does not teach or remotely suggest the invention defined by the present claims.

The Mehlem reference does not fill the gaps left by Hirai et al.

Mehlem discloses a pharmaceutical composition containing "Peptichemio" a complex series of peptides containing m-L-sarcolysine, and a cyclodextrin carrier that serve to regulate the bioavailability of Peptichemio. The Peptichemio peptides are specific oligopeptides having from 3 to 5 amino acids and are useful as chemotherapeutic agents in cancer therapy ([0002] to [0008].

There is no mention or suggestion in Mehlem that α-cyclodextrin enhances the biological activity of LH-RH peptide analogues when a composition comprising α-cyclodextrin and an LH-RH peptide analogue is administered orally.

For the reasons stated above, the Hirai et al and Mehlem references do not teach or suggest the invention defined by

the present claims. Accordingly, the rejection under 35 U.S.C. 103(a) should be withdrawn.

In view of the deficiencies in the art, claims 21-28, 32-41, 45-52, 58-65, and 66-78 are not *prima facie* obvious to one of ordinary skill in the art and, accordingly, withdrawal of the rejection under 35 U.S.C. 103(a) with respect to these claims is respectfully requested.

Applicant submits that the present application is now in condition for allowance and early notice of such action is earnestly solicited. If any final points remain that can be clarified by telephone, Examiner Snedden is respectfully encouraged to contact Applicant's attorney at the number indicated below.

Applicants hereby petition the Commissioner for Patents to extend the time for reply to the notice dated December 16, 2004 for three (3) months from March 16, 2005, to June 16, 2005. A duly completed credit card authorization form is attached to effect payment of the extension fee.

Respectfully submitted

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